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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,451

08/03/2006

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604-782

9016

23117 7590 09/15/2008
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EXAMINER

BHATIA, AARTI

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,451	Applicant(s) BYRNE ET AL.	
	Examiner Aarti Bhatia	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6.19.2006, 10.10.2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is the initial Office Action based on the 10/583,451 application filed on 6/19/2006.

Claims 1-17, as amended on 6/19/2006, are currently pending and have been considered below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,283,941 to Schoenfeld et al.

Schoenfeld discloses the following:

1. A syringe (10) comprising: (a) a barrel (12) having a cylindrical interior surface substantially free of discontinuities over its usable extent (see 12 in figure 1); (b) a plunger (14) including a plunger head (44) and a shaft (28); (c) a restrictor bobbin (40) movable with respect both to the barrel and the shaft to permit the drawing up and delivery of a fluid over the usable extent of the barrel, whilst limiting further use of the syringe; (d) the restrictor bobbin and/or shaft together comprising one or more members which are freely movable with respect to each other over a limited distance which is smaller than the usable extent of the barrel so as to permit repeated distal and proximal cycles of movement of the plunger head over the said limited distance (see figure 1).

2. A syringe as claimed in claim 1 wherein the said members which are freely relatively movable to permit repeated movement of the plunger head comprise the complete restrictor bobbin, the complete plunger shaft, or a part or parts of either or any combination thereof (see figure 1).

3. A syringe as claimed in claim 1 wherein the said movable member(s) comprise or may be provided by deformable portions of the bobbin or shaft, which are preferably resiliently deformable (column 18, lines 53-55).

4. A syringe as claimed in claim 1 wherein the said repeated movement of the plunger head is permitted at least when the plunger head is at or adjacent a proximal end of the said usable extent of the barrel.

5. A syringe as claimed in claim 1, wherein the said repeated movement of the plunger head is permitted at substantially every relative position of the plunger and barrel over the said usable extent of the barrel (see figure 1).

6. A syringe as claimed in claim 1 wherein the said free movement of the bobbin and shaft with respect to each other is permitted in a first region of the shaft and resisted in a second region of the shaft (see figure 8).

10. A syringe as claimed in claim 1 wherein the restrictor bobbin incorporates a projection, tine, tang, barb, serration or other like formation or member in engagement with the barrel interior wall to resist motion in one direction and permit motion in the opposite direction (see figure 11).

11. A syringe as claimed in claim 1 wherein the plunger is provided with formations (30) for restricting the movement of the restrictor bobbin with respect to the plunger shaft.

12. A syringe as claimed in claim 1 wherein the plunger shaft is formed with a first region over which unrestricted movement of the shaft with respect to the restrictor bobbin is possible and a second region over which movement of the shaft with respect to the restrictor bobbin is substantially restricted to unidirectional movement (see figure 8).

13. A syringe as claimed in claim 1 wherein the restrictor bobbin comprises two or more relatively slidable or relatively deformable parts (see figure 9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7-9 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenfeld et al.

With respect to claims 7-9, Schoenfeld discloses a syringe as claimed in claim 1, but fails to teach specific distances and volumes over which the movement of the plunger head is possible.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the working ranges of the plunger, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 14-17, Schoenfeld discloses a syringe as claimed in claim 1 including wherein the bobbin incorporates a restrictor member for restricting movement of the plunger with respect to the bobbin or the bobbin with respect to the

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barrel, and wherein the direction in which such movement is restricted is reversible (see figures 9-11), but fails to teach the packaging or contents of the syringe.

It would have been obvious to one having ordinary skill in the art to pack the syringe either with the plunger depressed or retracted, and for the syringe to contain a diluent liquid, as these are very commonly done in the art of syringes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763